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मानक

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“The Right to Information, The Right to Live”

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“Step Out From the Old to the New”

IS 6442 (1989): Thoracic Surgery Instruments - Shears, Rib, Tudor Edward's Pattern, for Posterior End of Ribs [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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"पुनर्गुष्ट १९९४"
"RE-AFFIRMED 1994"

IS 6442 : 1989

Indian Standard

THORACIC SURGERY INSTRUMENTS —
SHEARS, RIB, TUDOR EDWARD'S PATTERN,
FOR POSTERIOR END OF RIBS —
SPECIFICATION

(First Revision)

भारतीय मानक

छाती सम्बन्धी शल्यक्रिया उपकरण — पसली कैंची, ट्यूडर एडवर्ड नमूने की,
पसली के पिछले सिरे के लिए

(पहला पुनरीक्षण)

UDC 615.472.3 : 616.712.1 - 089

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

December 1989

Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1972. In this revision, tolerances on various dimensions have been specified and the requirements for surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

THORACIC SURGERY INSTRUMENTS — SHEARS, RIB, TUDOR EDWARD'S PATTERN, FOR POSTERIOR END OF RIBS — SPECIFICATION (First Revision)

1 SCOPE

This standard prescribes requirements and tests for Tudor Edward's pattern rib, shears used for posterior end of ribs in thoracic surgery.

2 REFERENCES

<i>IS No.</i>	<i>Title</i>
IS 1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV5 to HV100 (<i>second revision</i>)
IS 3642 : 1978	General requirements for surgical instruments (<i>first revision</i>)
IS 4905 : 1968	Methods for random sampling
IS 6603 : 1972	Specification for stainless steel bars and flats
IS 7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 MATERIALS

3.1 Working Jaws

The working jaws shall be made of stainless steel conforming to Designation 40Cr13 of IS 6603 : 1972.

3.2 Handles, Screws and Spring

The handles, screws and spring shall be made of stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS 6603 : 1972.

4 SHAPE AND DIMENSIONS

4.1 The shape and dimensions of the instrument shall be as shown in Fig. 1.

4.1.1 The tolerances on linear dimensions shall be as specified below:

- ± 0.05 mm on dimensions up to 2.0 mm;
- ± 0.1 mm on dimensions above 2.0 mm and up to 5.0 mm,
- ± 0.2 mm on dimensions above 5.0 mm and up to 20.0 mm,
- ± 0.5 mm on dimensions above 20.0 mm and up to 50.0 mm,
- ± 1.0 mm on dimensions above 50.0 mm and up to 100.0 mm, and
- ± 2.0 mm on dimensions above 100.0 mm.

4.1.2 Tolerances on angular dimensions shall be $\pm 2^\circ$.

4.1.3 The two halves of the instrument shall, not differ at any dimension and shall match with each other perfectly.

5 HEAT TREATMENT

The working jaws shall be hardened and tempered to a hardness of 500 to 600 HV, the spring to 420 to 470 HV and other components to 380 to 420 HV, when tested in accordance with IS 1501 (Part 1) : 1984.

5.1 Mating surfaces of the same instrument, such as, opposite jaws and shanks, shall not vary in hardness by more than 40 HV.

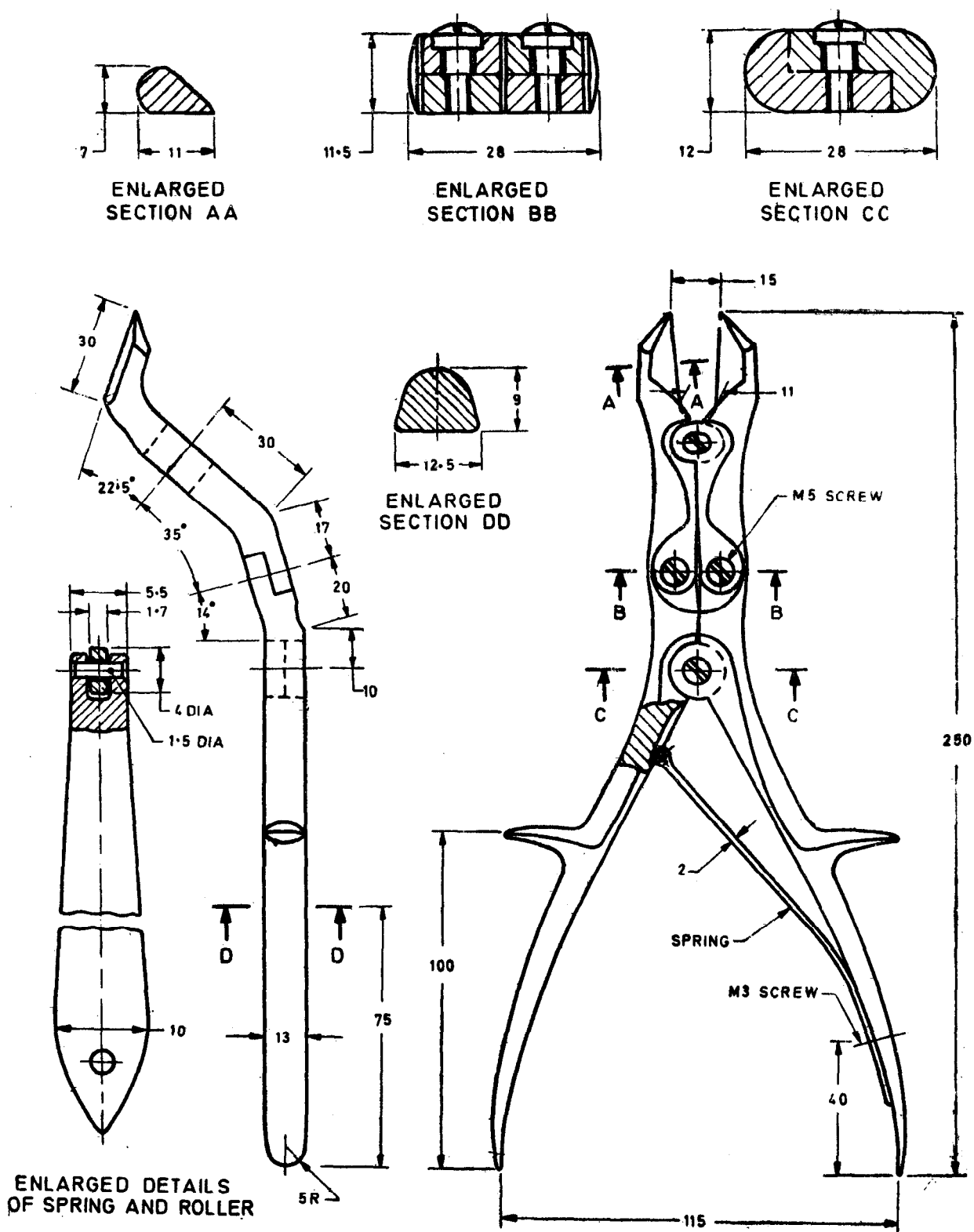
6 WORKMANSHIP

6.1 The opening and closing of the jaws and the movement of the handles shall be smooth and jerk free. The cutting edges shall register accurately.

6.2 The joints shall conform to the relevant requirements of 6 of IS 3642 : 1978.

6.3 All edges shall be rounded except the cutting edges which shall be sharp and uniform. The cutting edges shall not have nicks, jags and waviness when examined under a magnification of 10 X.

6.4 The spring shall function satisfactorily.



All dimensions in millimetres.

FIG. 1 SHEARS, RIB, TUDOR EDWARD'S PATTERN, FOR POSTERIOR END OF RIBS

7 SURFACE CONDITION

7.1 General

All surfaces shall be free from pores, crevices and grinding marks. The instruments shall be free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

7.2 Surface Finish

The surface finish shall be one of, or a combination of the following:

- a) Mirror polished; and
- b) Reflection-reducing, for example, satin finish, matt black finish.

NOTES

1 The satin finish should be achieved by an appropriate procedure, such as, grinding, brushing, electropolishing, and in addition, satin finishing (glass beading or satin brushing). The finish should be uniform, smooth and it should reduce glare.

2 Instruments of mirror finish should be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish should be achieved by an appropriate procedure, such as, polishing, brushing, electropolishing, and mirror buffing.

7.3 Passivation and Final Treatment

The instruments shall be treated by a suitable passivation process, for example, by electropolishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

8 TESTS

8.1 Performance Test

8.1.1 The shears shall be used to cut a 3 mm thick piece of tanned leather. The entire length of the cutting edge shall cut the leather. This shall be done 5 times. The cuts shall be clean and neat and the cutting edges of the instrument shall not get damaged.

8.1.2 The shears shall be used to cut a fresh piece of rib of a fully grown sheep or goat, the length of the cut being not less than one-half the length of the cutting edges. The rib shall be cut

evenly without any splintering. This shall be done 5 times. The cuts shall be clean and neat and the cutting edges of the instrument shall not get damaged. The cutting edges shall continue to register accurately after the test.

8.2 Load Closure Test

The cutting edges shall just meet along their entire length when a force of 15 N (1.5 kgf approximately) is applied at the free end of the handles.

8.3 Test for Flexibility of Spring

With the handle of the shears fully open, the distance between the free ends of the handle shall be measured. By applying force at the handle, the shears shall be closed and opened 15 times in quick succession. The distance between the free ends of the handle shall be measured again. There shall be no change in the distance as recorded at the beginning of the test.

8.4 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975. They shall show no sign of corrosion after the test.

9 MARKING AND PACKING

9.1 The instrument shall be legibly and indelibly marked with the manufacturer's name, initials or recognized trade-mark; the word's 'Stainless Steel' or letters 'SS', and the country of manufacture.

9.2 Each instrument shall be wrapped in a suitable cushioning material, namely, folded tissue paper. It shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

9.2.1 Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

9.3 The packages shall be marked with the name of the instrument; the manufacturer's name, initials or recognized trade-mark; the words 'Stainless Steel'; and the country of manufacture.

10 SAMPLING

The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

ANNEX A

(Clause 10)

**SAMPLING OF SHEARS, RIB, TUDOR EDWARD'S PATTERN,
FOR POSTERIOR END OF RIBS****A-1 LOT**

In any consignment, all the instruments produced from identical material under similar conditions and having the same surface finish shall constitute a lot.

A-2 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling

(Clauses A-2, A-3.1 and A-3.2)

Lot Size	Sample Size	Sub-sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3

A-2.1 These instruments shall be selected from the lot at random and in order to ensure

randomness of selection, procedure given in IS 4905 : 1968 may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship, and surface condition (visual), and tested for mass and engagement of jaws. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

A-3.2 The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1**. Each instrument in the sub-sample shall be subjected to hardness, performance, load closure, flexibility of spring and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification if none of the instruments in the sub-sample fails in any of these tests.

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BUREAU OF INDIAN STANDARDS

Headquarters :

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :

	Telephone
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	{ 331 01 31 331 13 75
Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola CALCUTTA 700054	36 24 99
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	{ 2 18 43 3 16 41
Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113	{ 41 24 42 41 25 19 41 29 16
Western : Manakalaya, E9 MIDC, Marol, Andheri (East) BOMBAY 400093	6 32 92 95
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